



Baxter Healthcare Corporation  
One Baxter Parkway, DF3-1W  
Deerfield, IL 60015-4633

November 25, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. OOD-1539: Draft Guidance for Industry; Electronic Records; Electronic Signatures, Maintenance of Electronic Records

I am writing on behalf of the Baxter Healthcare Corporation 21 CFR Part 11 Working Group.

We have reviewed the subject document in detail and have developed several comments, both general and specific. All of these comments are contained in the attached table.

We hope that our comments prove beneficial. Please contact me with any questions regarding these comments.

Sincerely,

A handwritten signature in black ink that reads "Johnny Long". The signature is fluid and cursive.

Johnny Long  
Director, Quality Systems  
Baxter Healthcare Corporation

Attachments:

- 1) Table: Comments for Draft Guidance for Industry, Electronic Records; Electronic Signatures, Maintenance of Electronic Records
- 2) Line Numbered Copy of DRAFT Guidance for Industry, Electronic Records; Electronic Signatures, Maintenance of Electronic Records

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